

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION)
_____)

MDL No. 2419
Dkt. No 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:)

All Cases)
_____)

**TENNESSEE CLINIC DEFENDANTS' RESPONSE TO
AMERIDOSE, LLC'S MOTION TO PROCEED WITH FDA-AUTHORIZED
DESTRUCTION OF RECALLED INVENTORY [DKT. 1090]**

Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John W. Culclasure, MD; Debra V. Schamberg, RN; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "the Tennessee Clinic Defendants"), file this *Response to Ameridose, LLC's Motion to Proceed with FDA-Authorized Destruction of Recalled Inventory [Dkt. 1090]*.

RESPONSE

On April 11, 2014, Ameridose, LLC ("Ameridose") filed a motion seeking permission to destroy all of the drugs and other products it recalled in 2012 ("the Motion").

Because, to date, Ameridose has refused to engage in any discovery, the Tennessee Clinic Defendants sent Ameridose a letter on April 18, 2014, requesting some information that would permit them to evaluate whether the recalled drugs were relevant in the suits naming the Tennessee Clinic Defendants (and Ameridose).

Ameridose is a defendant in all or virtually all of the suits naming the Tennessee Clinic Defendants.

Ameridose agreed to provide a small subset of the information requested, namely, information regarding the types and amounts of drugs in the recalled inventory Ameridose sought to destroy. However, Ameridose refused to provide the bulk of the information requested. Based on the information provided, the Tennessee Clinic Defendants agreed not to oppose the destruction of controlled substances in the inventory, accounting for roughly half of the total drugs.

The scope of discovery is broad:

“Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense.... Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.”¹

Notwithstanding this clear mandate, to date, no discovery of Ameridose has occurred, and Ameridose has repeatedly opposed all efforts to obtain discovery from it.

Ameridose's position appears to be that it should not be subjected to any discovery, or even be a party to this case, because NECC, not Ameridose, compounded the MPA at issue. The fact remains, however, that Ameridose IS a party to the case, and is an entity owned by the exact same people as NECC, engaged in the exact same line of business, with allegedly overlapping operations and employees.

The latter points are key for the purposes of the Motion. Discovery regarding the common ownership of the two entities and the respective roles of each owner at Ameridose and NECC may reveal, for example, that Barry Cadden oversaw compounding at both businesses. If that (or something similar) proves true, the

¹ Fed. R. Civ. P. 26(b)(1).

Tennessee Clinic Defendants may wish to test some of the recalled inventory from Ameridose, as expressly permitted by Fed. R. Civ. P. 34, to see if Mr. Cadden was able to properly carry out his oversight obligations at Ameridose. The Tennessee Clinic Defendants intend to assert comparative fault against Mr. Cadden. This information would certainly be relevant to his culpability and his overall ability to properly supervise compounding operations.

However, Ameridose has refused to provide the Tennessee Clinic Defendants with any information regarding the role of NECC's owners at Ameridose.

Likewise, the two companies may have shared standard operating procedures for compounding sterile medications or purchased from the same suppliers of raw product or vials. The Tennessee Clinic Defendants are unaware of any conclusive determination as to the actual source of the contamination of NECC's MPA. Testing medications from Ameridose compounded using the same supplies or processes may help resolve this crucial causation issue.

Again, Ameridose has refused to provide the Tennessee Clinic Defendants with any information regarding its compounding process or suppliers.

Simply put, without any discovery from Ameridose, it is virtually impossible to evaluate how relevant these medications may or may not be. Ameridose should not be permitted to refuse to engage in any discovery while simultaneously destroying potentially-discoverable evidence.

The Tennessee Clinic Defendants are sensitive to the burden on Ameridose of preserving the recalled inventory. They have already agreed to the destruction of the controlled substances in the inventory, which accounted for roughly half of the total

inventory. The Tennessee Clinic Defendants offered to allow Ameridose to destroy the vast majority of the remaining inventory, according to the following parameters.

Ameridose would preserve:

1. The minimum number of vials necessary for sterility testing pursuant to USP 71 (*i.e.*, 20 vials for lots of 500 or more vials),
2. From lots of sterile preparations,
3. Compounded between May 21, 2012, and August 10, 2012 (the same time period as the three contaminated lots of methylprednisolone acetate from NECC), and
4. Any lots of medications containing methylprednisolone in their entirety.

Any lots with less than the number of vials required for sterility testing pursuant to USP 71 may be destroyed, except those containing methylprednisolone.

Ameridose refused this reasonable compromise and refused to offer a counter-proposal. Ameridose also failed to provide any estimate of the total number of vials that would need to be preserved under the proposal or the estimated cost of preservation. All the Tennessee Clinic Defendants received in response was a blanket refusal, citing the unspecified cost of identifying and segregating this small subset of medications.

Additionally, the Tennessee Clinic Defendants do not suggest that preservation be indefinite, only until Ameridose has engaged in some discovery. The Tennessee Clinic Defendants propose that Ameridose be permitted to dispose of the subset medication described above if the Tennessee Clinic Defendants have not tested, or requested permission to test, the medications within 30 days after Ameridose responds to the first round of written discovery propounded by the Tennessee Clinic Defendants.

That will give the Tennessee Clinic Defendants the opportunity to obtain and analyze the information they need to determine whether the medications are relevant, without imposing an indefinite burden on Ameridose.

WHEREFORE, the Tennessee Clinic Defendants respectfully request, that *Ameridose, LLC's Motion to Proceed with FDA-Authorized Destruction of Recalled Inventory [Dkt. 1090]*, be granted in part and denied in part, consistent with the parameters proposed above.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

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* Admitted pursuant to MDL Order No. 1.

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CERTIFICATE OF SERVICE

I certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 25th day of September, 2014.

/s/ Chris J. Tardio

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